

What is claimed is:

1. A two-layer external breast prosthesis, comprising:
  - a) a first inner layer comprised of a self-shaping dispersion, said dispersion having a specific gravity of less than 1.0; and
  - b) a second outer layer comprised of an elastic material, wherein said second outer layer is stiffer than said first inner layer.
2. The prosthesis of claim 1, wherein the elastic material of said second outer layer comprises a silicon gel.
3. The prosthesis of claim 1, wherein the elastic material of said second outer layer is heat cured.
4. The prosthesis of claim 1, wherein the self-shaping dispersion of said first inner layer is uncured and comprised of a silicone oil and a plurality of microspheres.
5. The prosthesis of claim 4, wherein the silicone oil has a viscosity of approximately 500 CSt.
6. The prosthesis of claim 4, wherein the plurality of microspheres are comprised of an acrylonitrile copolymer and have an average particle size of from approximately 40 microns to approximately 125 microns.
7. The prosthesis of claim 1, further comprising a film wall separating said inner layer and said outer layer.
8. The prosthesis of claim 1, wherein said inner layer is confined within a first film envelope, and wherein said outer layer is confined within a second film envelope.

9. The prosthesis of claim 8, wherein the said first and second film envelopes share a common film wall therebetween.
10. The prosthesis of claim 8, wherein said first and said second film envelopes each comprise a polyurethane film.
11. The prosthesis of claim 1, wherein said inner layer is confined within a first film envelope and is sufficiently soft to yield to the touch, and wherein said outer layer is sufficiently stiff to substantially prevent wrinkling of a second film envelope confining said outer layer.
12. The prosthesis of claim 1, wherein said outer layer is sufficiently stiff to generally retain the shape of a human breast.
13. A two-layer breast prosthesis, comprising:
  - a) a first film envelope configured to define a first interior volume;
  - b) a second film envelope joined to the first film envelope along a common side edge to thereby define a second interior volume wherein said second film envelope and first film envelope share a common film wall;
  - c) a first and a second sealed fill opening, respectively, extending from the common side edge of the first film envelope and the second film envelope to the respective first and second interior volumes;
  - d) a first material within said first film envelope forming an interior body portion of the prosthesis, said first material comprising a self-shaping material; and
  - c) a second material within said second film envelope forming an exterior body portion of the prosthesis, said second material comprising an elastic material.

14. The prosthesis of claim 13, wherein the self-shaping material of d) is a self-shaping dispersion comprised of a silicone oil and a plurality of microspheres.
15. The prosthesis of claim 13, wherein said self-shaping material of d) is constructed and arranged to be yieldably shaped by a patient's chest wall.
16. The prosthesis of claim 14, wherein the respective plurality of microspheres have an average particle size of from 40 microns to 125 microns.
17. The prosthesis of claim 14, wherein said microspheres are comprised of an acrylonitrile copolymer.
18. The prosthesis of claim 14, wherein said microspheres are filled with isobutane.
19. The prosthesis of claim 13, wherein the first material of d) has a specific gravity less than approximately 1.
20. A process for manufacturing a two-layer breast prosthesis comprising the steps of:
  - a) providing: (i) a first film envelope configured to define a first interior volume; and (ii) a second film envelope joined to the first film envelope along a common side edge to thereby define a second interior volume wherein said second film envelope and said first film envelope share a common interstitial film wall and wherein said first and said second film envelopes further comprise a respective first and a second fill opening extending from the common side edge of the respective first and second film envelopes to the respective first and second interior volumes;
  - b) at least partially filling the second interior volume of step a) by passing a curable elastic material precursor through the second fill opening;

- c) at least partially filling the first interior volume of step a) by passing a self-shaping dispersion through the first fill opening; and
  - d) sealing the first and second fill openings.
21. The process of claim 20, further comprising heat treating the joined first film envelope and second film envelope in a mold having a surface design configured to a desired shape of a breast to thereby cure the elastic material precursor in the second film envelope and to provide a two-layer breast prosthesis having the desired breast shape.
22. The process of claim 20, wherein step d) further comprises sealing the first and second fill openings spontaneously.
23. The process of claim 20, wherein step a) further comprises sealably affixing an interstitial plastic film extending between and to a first and a second exterior plastic film, respectively, along their respective common edges to thereby form the first film envelope and the second film envelope joined to the first film envelope.
24. The process of claim 23, wherein the interstitial plastic film and the first and second exterior films are each comprised of polyurethane.
25. The process of claim 20, wherein the elastic material of step b) is a silicone gel.
26. The process of claim 20, wherein the self-shaping dispersion of step c) comprises a silicone oil and a plurality of microspheres.